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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,191	09/17/2003	Laszlo Prokai	UF-300XC2	8784

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EXAMINER
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RADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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06/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/666,191

**Applicant(s)**

PROKAI ET AL.

**Examiner**

Barbara P. Badio, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,8,10-12,14,20 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,10-12,14,20 and 26-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

**Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Double Patenting***

2. The rejection of claims 7, 9, 13, 15-19 and 21-25 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,186,707(i.e., Application No. 10/731,528) is made moot by the cancellation of the instant claims.

3. The rejection of claims 1-6, 8, 10-12, 14 and 20 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,186,707(i.e., Application No. 10/731,528) is maintained.

Applicant argues the cited patent does not teach or suggest the instantly claimed invention. Applicant's argument was considered but not persuasive for the following reason.

Applicant's attention is directed to page 10, lines 14-15 of the present specification. The specific diseases of the cited patent, like those of instant claims 10-12, are encompassed by the instant invention.

For this reason and those given in the previous Office Action, the rejection of claims 1-6, 8, 10-12, 14 and 20 on the ground of nonstatutory obviousness-type double

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patenting over claims of US Patent No. 7,186,707(i.e., Application No. 10/731,528) is maintained.

### ***Claim Objections***

**4. The objection to claims 9, 18, 19, 24 and 25 under 37 CFR 1.75 as being substantial duplicates of claims 1, 14 and 20 is made moot by the cancellation of the instant claims.**

**5. The objection to claim 2-6 under 37 CFR 1.75 as being substantial duplicates of claim 1 is maintained.**

Applicant argues the objection to the instant claims is moot in view of the amendment. Applicant's argument was considered but not persuasive for the following reason.

As indicated in the previous Office Action, the method via which the quinol is converted or the undesirable side effect which is minimized does not provide further limitation of the claimed invention. It is noted that the recitation of the biologically active estrogen compound produced does not further limit the scope of the claimed method.

### ***Claim Rejections - 35 USC § 112***

**6. The rejection of claim 9 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement, is made moot by the cancellation of the instant claim.**

**7. The rejection of claims 1-6, 8 and 10-12 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn.**

8. Claims 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The present specification lacks description/disclosure of the claimed isomeric form of the disclosed quinol and, thus, does not convey to the skilled artisan in the art that applicant, at the time the application was filed, had possession of the claimed invention.

**9. The rejection of claim 9, 18, 19, 24 and 25 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claims.**

**10. The rejection of claim 1-6, 8 and 10-12 under 35 USC 112, second paragraph is withdrawn.**

***Claim Rejections - 35 USC § 102***

- 11. The rejection of claim 9 under 35 USC 102(b) over Jiu (US 2,910,486) is made moot by the cancellation of the instant claim.**
- 12. The rejection of claims 1-8 under 35 USC 102(b) over Jiu (US 2,910,486) is withdrawn.**
- 13. The rejection of claims 15, 17-19 and 21-25 under 35 USC 102(b) over Numazawa et al. is made moot by the cancellation of the instant claim.**
- 14. The rejection of claims 14 and 20 under 35 USC 102(b) over Numazawa et al. is withdrawn.**
- 15. The rejection of claims 23-25 under 35 USC 102(b) over Ohe et al. is made moot by the cancellation of the instant claim.**
- 16. The rejection of claims 14 and 20 under 35 USC 102(b) over Ohe et al. is withdrawn.**
- 17. The rejection of claims 17-19 under 35 USC 102(b) over Jiu (US 2,950,291) is made moot by the cancellation of the instant claim.**

**18. The rejection of claims 14 and 20 under 35 USC 102(b) over Jiu (2,950,291) is withdrawn.**

19. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Sedee et al. (Tetrahedron Letters, 1983).

Sedee et al. teaches 10,17-dihydroxy-19-norpregna-1,4-dien-20-yn-3-one (see page 5780, compound VI). The compound taught by the reference is encompassed by the instant claim.

20. Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Nali et al. (J. Molecular Catalysis, 1987).

Nali et al. teaches 10,17-dihydroxy-estra-1,4-dien-3-one (see the attached Abstract). The compound taught by the reference is encompassed by the instant claim.

***Claim Rejections - 35 USC § 103***

**21. The rejection of claims 7 and 9 under 35 USC 103(a) over Jiu (2,910,486) is made moot by the cancellation of the instant claims.**

**22. The rejection of claims 1-6, 8 and 10-12 under 35 USC 103(a) over Jiu (2,910,486) is withdrawn.**

23. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sedee et al. (Tetrahedron Letters, 1983).

Sedee et al. teaches 10,17-dihydroxy-19-norpregna-1,4-dien-20-yn-3-one (see page 5780, compound VI).

The instant claim differs from the reference by reciting a pharmaceutical composition comprising the prior art compound. However, the addition of a carrier or solvent to an unpatentable compound is prima facie obvious. Ex parte Douros, 163 USPQ 667.

24. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nali et al. (J. Molecular Catalysis, 1987).

Nali et al. teaches 10,17-dihydroxy-estra-1,4-dien-3-one (see the attached Abstract).

The instant claim differs from the reference by reciting a pharmaceutical composition comprising the prior art compound. However, the addition of a carrier or solvent to an unpatentable compound is prima facie obvious. Ex parte Douros, 163 USPQ 667.

#### ***Other Matters***

25. It is suggested that applicant delete the structure between claim 8 and 9 of said claims.



***Conclusion***

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

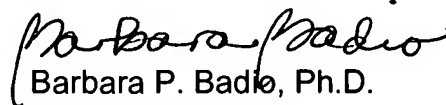
***Telephone Inquiry***

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Barbara P. Badlo, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
May 31, 2007